IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

TERESA L. STEVENS,
Plaintiff

v.

CIVIL ACTION NO. 2:16-CV-00265

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BOSTON SCIENTIFIC CORPORATION, EMAI PLASTIC RAW MATERIAL CO, LTD.., PROXY BIOMEDICAL LIMITED, AND LUXILON INDUSTRIES NV,
Defendants.

PLAINTIFF'S CLASS ACTION COMPLAINT

Plaintiff, Teresa L. Stevens ("Plaintiff"), by and through her attorney, brings this individual and class action complaint, pursuant to Rule 23 of the Federal Rules of Civil Procedure, against Defendant Boston Scientific Corporation ("BSC"), EMAI Plastic Raw Materials Co., Ltd. ("EMAI"), Proxy Biomedical Limited ("Proxy"), and Luxilon Industries NV ("Luxilon") (collectively "Defendants") for violations of RICO - 18 U.S.C. § 1962(c). Plaintiff also brings causes of action against Defendant BSC for fraud, intentional misrepresentation, negligent misrepresentation, violations of the West Virginia's Deceptive Trade Practices Act, unjust enrichment, and requests injunctive and declaratory relief. Plaintiff is simultaneously filing an expedited motion requesting a temporary restraining order and preliminary injunction to prevent immediate and irreparable injury, loss, or damage caused by Defendants' unlawful conduct. Plaintiff alleges the following upon information and belief, except as to those paragraphs pertaining to Plaintiff's own actions, which are alleged upon personal knowledge. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF ACTION

1. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on her own behalf and on behalf of a class (the "Class") of similarly situated entities and individuals (the "Class Members") who were implanted with Boston Scientific transvaginal mesh products after September, 2012.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 18 U.S.C. §§1961, 1962, 1964, 28 U.S.C. §§ 1331, 1332(a) and 1367. The Court has personal jurisdiction over defendants pursuant to 18 U. S. C. §1965 (a) (b) and (d) as Defendants transacted their affairs in this district and the ends of justice require that Defendants be brought before this Court.

3. Defendants have significant contact with this federal judicial district such that they are subject to the personal jurisdiction of the court in this district. This Court's assertion of jurisdiction over these Defendants is consistent with the notions of fair play and substantial justice. One or more Defendants purposefully availed themselves of the benefits of this State such that they could reasonably anticipate being haled into Court here, or otherwise directed their conduct toward this State such that the effects of their damages were occasioned upon this Plaintiff within this State.

4. This Court is a proper venue for this action pursuant to 18 U.S.C. §1965 (a) and 28 U.S.C. §1391 (a) and (b)(2). Venue is proper in this judicial district because it is where a substantial part of the events and omissions giving rise to Plaintiff's causes of action took place.

PARTIES

5. Plaintiff Theresa Stevens in an individual who is a citizen of the State of West Virginia and who resides in this judicial district. Stevens suffers from Pelvic Organ Prolapse and Stress Urinary Incontinence ("SIU"). Steven's urethral sling operation took place on October 27, 2014. Stevens was implanted with BSC Obtryx-Halo Urethral Sling System.

6. Defendant Boston Scientific Corporation is a foreign corporation organized under the laws of the State of Delaware and with its principal place of business in Marlborough, Massachusetts. BSC participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

7. Defendant EMAI Plastic Raw Materials, Inc. is a foreign corporation organized under the laws of China and with its principal place of business in Guangzhou, China. EMAI directed its business activities to the United States, including West Virginia, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

8. Defendant Proxy Biomedical Limited is a foreign corporation organized under the laws of Ireland and with its principal place of business in Galway, Ireland. Proxy directed its business activities to the United States, including West Virginia, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

9. Defendant Luxilon Industries NV is a foreign corporation organized under the laws of Belgium and with its principal place of business in Antwerpen, Belgium. Proxy directed its business activities to the United States, including West Virginia, and participated in

the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

SUBSTANTIVE ALLEGATIONS

Background Facts

I. Introduction

10. Boston Scientific manufactures and markets transvaginal mesh—a medical device designed to be permanently implanted into women's bodies. It is a lucrative business. On average, Boston Scientific generates $120,000,000 in revenue every year from the sale of its transvaginal mesh. Each year approximately 55,000 women receive a Boston Scientific mesh implant; so, somewhere today, about 200 women are being permanently implanted with Boston Scientific's transvaginal mesh. Advantage mesh, which Boston Scientific uses for all its mesh transvaginal mesh, is subject to regulation by the U.S. Food and Drug Administration ("FDA"), as well as other regulations and laws. BSC's Advantage mesh was made from Marlex HGX-030-1,[1] a specific and unique polypropylene, which was cleared by the FDA under its 510(k) approval process. At all relevant times, Marlex HGX-030-1 was manufactured and trademarked[2] by a joint venture between Chevron and Phillips/Sumika (Phillips) in LaPorte, Texas. Marlex is sold in its raw form in pellets. By law, BSC is required to manufacture Advantage mesh from Marlex HGX-030-1.[3] If BSC used anything other than Marlex HGX-030-1 to form its mesh, the product would not be Advantage mesh, as approved by the FDA. In short, Phillips Marlex comprises Boston Scientific's Advantage mesh, which in turn comprises

[1] Exhibit 1, Marlex Property Data Sheet.
[2] Exhibit 2, Trademark Information for Phillips Sumika Marlex.
[3] Exhibit 3, BSCM04700050810 - BSCM04700050813; *see also* Exhibit 9, relevant portions of 510(k) submission packet for Advantage line.

Boston Scientific's transvaginal mesh products. If Boston Scientific cannot get Marlex, then it cannot make its transvaginal mesh that was cleared by the FDA.

11. In 2011 Boston Scientific began running out of Marlex. No Marlex? Then, no transvaginal mesh products, and no $120,000,000 in annual revenue. After failing to convince the manufacturer, Phillips, to sell it any more Marlex, Boston Scientific made the fateful decision to smuggle counterfeit Marlex out of China. Specifically, beginning in June, 2011 through fall 2012, and specifically including on or about August 16, 2011, May 16, 2012, July 10, 2012 and July 31, 2012, and thereafter, BSC smuggled counterfeit Marlex pellets out of China and into Belgium and the United States. The counterfeit Marlex pellets were then subjected to a manufacturing process.[4] Each step in the process knowingly transformed the counterfeit Marlex pellets into a different form of counterfeit Marlex.

- The counterfeit Marlex pellets (also called resin) were sent to Luxilon's facility in Belgium to produce counterfeit Marlex fibers (filament);
- The counterfeit Marlex fibers were then sent to Proxy in Galway, Ireland to make counterfeit mesh using the counterfeit Marlex;
- The counterfeit mesh was formatted at Proxy to shape and sent to Medventure in Indiana to further shape in preparation for final knitting of counterfeit mesh manufactured with the counterfeit Marlex; and,
- The mesh knitting for the counterfeit mesh was completed at Medventure.[5]

12. Plaintiff and Class Members were implanted with counterfeit mesh made from counterfeit Marlex pellets smuggled out of China and illegally imported into the United

[4] Exhibit 4, BSCM11500006055 – BSCM11500006064.
[5] Exhibit 5, 104_0001 – 104_0004.

States. BSC estimates that its sale of its mesh and supporting products result in income to BSC of over $120,000,000 each year.[6]

13. Most of this sordid story is told using BSC's own documents. Unfortunately, BSC has improperly labeled the vast majority of its documents produced as confidential – to conceal from the injured women and the public its illegal smuggling of counterfeit Marlex pellets and sale of counterfeit mesh.

14. Plaintiff's recitation of facts is complicated by BSC's bad faith in the Southern District of West Virginia and, more specifically, its MDL for mesh litigation. There, before the Honorable Judge Goodwin, BSC produced hundreds of thousands of documents, and in blatant bad faith stamped the vast majority (if not all) as "confidential" (or "highly confidential") regardless of whether it had any good faith basis to do so under the controlling stipulated protective order. Indeed, BSC improperly redacted thousands of these documents in further violation of court orders and Federal Rules of Civil Procedure. Moreover, BSC provided a woefully inadequate and inaccurate privilege log to further obfuscate and conceal its misconduct. BSC continues to hide all these documents from the public. The public, not to mention the hundreds of thousands of women who were (or will be) implanted with Boston Scientific's counterfeit, adulterated mesh, have a right to know.

II. The Players in this Saga

a. <u>The Injured Women.</u>

15. Plaintiff and Class Members have suffered damages. These women sought to acquire legal, safe, authentic, adequately tested mesh for permanent implantation into their

[6] Exhibit 6, BSCM13000000033.

bodies. Instead, Defendants provided Plaintiff and Class Members with a counterfeit, adulterated product—now their mesh, which is now their property—worth far less than bargained. Worse, this counterfeit, adulterated mesh is not just part of Plaintiff's and Class Members' property, it is permanently part of their bodies.

b. Boston Scientific

16. BSC has a public face and a private face. Publicly, BSC represents that it's a "leading innovator of medical solutions that improve the health of patients around the world."[7] BSC claims it places its patients first.[8] Caring, it says, is its number one core value.[9] Excellence is inherent is everything we do, it claims.[10] Integrity is a key word it uses to describe itself.[11] BSC claims that it is dedicated to women's health – it claims nothing is more important than women's health.[12] BSC estimates as many as 28 million women suffer from incontinence and prolapse. Capitalizing on these women's medical problems, BSC's own numbers suggest that at least 1,000 women receive BSC mesh products every week. Right now, it is likely another woman is being implanted with Boston Scientific mesh—Boston Scientific's counterfeit, adulterated mesh.

17. BSC's actions (albeit concealed) speak far louder than its warm words to the public. BSC's public image starkly contrasts its decision to lie to Chinese customs, to U.S. Customs, to the FDA, and to every woman in America who has received a BSC mesh product since September, 2012. The image it projects differs considerably from the image

[7] Exhibit 6A, https://www.bostonscientific.com/en-US/about-us.html
[8] *Id.*; Exhibit 6B, http://www.bostonscientific.com/2014ar/.
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*

of a medical device company that has recalled 793 products since 2003,[13] has operated secret plants[14] and has been fined hundreds of millions of dollars repeatedly by the U.S. and other governments.[15]

c. Marlex HGX-030-1 Pellets

18. To gain FDA clearance, BSC represented to the FDA it used Marlex HGX-030-1 to make Advantage mesh - the backbone of the BSC SUI product group (Advantage, Obtryx, Lynx and Solyx and all its transvaginal mesh products).[16] Authentic Marlex pellets were manufactured by a joint venture of Chevron and Phillips.[17] Marlex is not a generic name (like "soft drink"). As previously stated, Marlex is a trademarked specific brand (like "Coke") and is identified in the industry as Marlex HGX-030-1.[18]

19. For several years, Phillips has issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene of all grades.[19] BSC was aware of the Marlex MSDS at all relevant

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[13] Exhibit 6C, Search results of recalled Boston Scientific products obtained from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

[14] Exhibit 7, http://www.boston.com/business/technology/biotechnology/articles/2004/09/27/suit_accuses_stent_maker_of_copying_designs?pg=full.

[15] Exhibit 8, http://www.justice.gov/opa/pr/medical-device-manufacturer-guidant-sentenced-failure-report-defibrillator-safety-problems.

[16] *See* Exhibit 3; *see also* Exhibit 9, relevant portions of Advantage Surgical Mesh 510(k) Pre-Market Notification submission packet.

[17] Exhibit 9A, Marlex HGX-030-1 is now discontinued. It was manufactured for use in products like woven industrial fabric and bags, wovan carpet backing, woven bags and rope. Ultimately, unfortunately, BSC sought to permanently implant it into women's bodies. http://www.matweb.com/search/datasheettext.aspx?matguid=33893162c575403e83fab2c6e1fe8042.

[18] Exhibits 1 - 2.

[19] Exhibit 10, Marlex Material Safety Data Sheets from 2004 and 2008; *see also* Exhibit 11, U. Klinge, B. Klosterhalfen, M. Muller, A. P. Ottinger, V. Schumpelick, *Shringin of Polypropylene Mesh in vivo: An Experimental Study in Dogs*, 164 Eur J Surg 965, 965-969 (1998) (discussing how Marlex polypropylene degrades quickly in dogs).

times including when it manufactured and marketed its mesh products to Plaintiff and Class Members. The MSDS contains the following warning:

> "MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES."

(emphasis supplied).[20]

20. In 2005, Phillips terminated its contract with BSC for Marlex HGX-030-1 because the product was not intended for use in permanent implant devices.[21] In 2005, Phillips only allowed BSC to buy an additional 4,000 pounds of Marlex HGX-030-1. After that, as far as Phillips was concerned, Boston Scientific was cut off from getting any more authentic, Phillips Marlex to permanently implant into women.

21. In 2011, BSC's supply of Marlex resin began to run precariously low. BSC projected it would run out of this critical component of mesh by August/September 2012.[22] If BSC wanted to maintain the $120,000,000 in annual mesh sales, it would need to find more

[20] *See* Exhibit 10.
[21] Exhibit 6, BSCM13000000033.
[22] Exhibit 12, BSCM06700722580.

resin— and fast. In July, 2011 BSC requested that Phillips make a "special run" of one million pounds of the Marlex resin. From that special run, BSC would take all the resin it needed to continue the current production (and profits) and sell the rest. On July 27, 2011, Phillips refused to sell Marlex to BSC "at any price."[23] It seemed that, as far as Phillips was concerned, "no" actually did mean no.

22. Phillips' adamant refusal created a "fire drill" at BSC—an alarm rang out at BSC as the impending Marlex shortage would cripple BSC's mesh profits.[24] Quite simply, $120,000,000 per year hung in the balance, not to mention the continued existence of Boston Scientific's transvaginal mesh division.[25] BSC feverishly began researching alternative resin products.[26] Time—and authentic, Phillips Marlex—was running short.

III. The FDA Required that Advantage Mesh be Manufactured with Authentic Marlex Pellets.

23. BSC's Advantage Mesh, Advantage Fit, and Lynx Systems were cleared for sale by the FDA through its 510(k) process on or about April 2, 2002.[27] To gain clearance under the FDA's 510(k) process, a manufacturer must prove that the product it attempts to put on the market is substantially equivalent to predicate devices cleared by the FDA. BSC specified that the mesh would be made from Marlex HGX-030-1 and that its predicate

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[23] *Id.*

[24] Exhibit 13, BSCM06700722854.

[25] BSC asked Philips to reconsider its decision not to sell the Marlex to BSC. BSC offered Phillips more money for the resin and even indemnity to protect Phillips from any liability which may result from the sale of the Marlex to BSC. However, Phillips told BSC that Phillips would not sell the Marlex resin to BSC at any price. In its desperation, BSC even considered contacting a third party to procure the resin from Philips and give it to BSC. None of these efforts were successful.

[26] Exhibit 6, BSCM13000000033.

[27] Exhibit 3, BSCM04700050810 - BSCM04700050813. Advantage, Advantage Fit & Lynx Systems (K020110) (Boston Scientific) received their class II substantial equivalence designation on 4/3/2002.

devices were Tension Free Vaginal Tape ("TVT"), BioSling, Mentor Suspend Sling, and BSC's Trelex Mesh.[28] In 2004, BSC's Obtryx and Prefyx Systems obtained 510(k) clearance (No. K040787) citing Advantage Mesh, Advantage Fit, and Lynx Systems as its predicate devices.[29] In short, Plaintiffs' and Class Members' mesh products, as well as all its transvaginal mesh products from Boston Scientific were cleared through the FDA's abbreviated 510(k) process that is cheaper and easier than the more rigorous approval process. This abbreviated 510(k) process requires a finding of "substantial equivalence" to the prior device. Of course, Boston Scientific's prior devices contained Phillips' Marlex, which Boston Scientific needed to maintain the facade of its products' "substantial equivalence," including the mesh sold to Plaintiff and Class Members.

24. Once BSC knew it could no longer obtain authentic Marlex from Phillips it considered whether the FDA would approve a mesh made from a different polypropylene. BSC internally concluded taking a new product through the FDA, an agency BSC thought disfavored mesh, would detrimentally impact BSC's profits.[30] BSC began to research alternative resin products but concluded that the FDA, in a "backdoor" way to get mesh off the market, would likely not approve an alternative to Marlex.[31] BSC decided that its only logical path forward was to find and buy more Marlex.[32] It was Marlex or bust. BSC considered three options to obtain the necessary Marlex: (1) ask Phillips to reconsider its refusal to sell to BSC, (2) purchase Marlex from another customer of

[28] *Id.*; *see also* Exhibit 9.
[29] Exhibit 14.
[30] Exhibit 13, BSCM06700722854.
[31] Exhibit 12, BSCM06700722580; Exhibit 15, BSCM06700008804.
[32] *Id.*

Phillips who had current inventory, or (3) purchase Marlex on the secondary market. Simply put, BSC feared the FDA would not approve an alternative to Phillips Marlex.[33]

25. To avoid FDA scrutiny and arguably comply with the law, BSC needed Phillips Marlex. The FDA approval for sale and use was premised on the Phillips Marlex.[34] BSC's internal documents make clear its concern that a change in the polypropylene would trigger FDA concerns that would lead to disapproval of all of the BSC mesh products at a cost of $120,000,000 annually to BSC. BSC scrambled to look to alternative sources to obtain the Marlex outside the U.S. Unfortunately, BSC's scrambled to China—and more specifically the Guandong area known at a leading counterfeiter in the world.

26. BSC acknowledged that sourcing Marlex from China was risky due to the prevalence of counterfeit products sold in China, but its desperation drove BSC to ultimately purchase 34,000 pounds of counterfeit Marlex pellets from EMAI, a known Chinese distributor of counterfeit plastic products.

IV. Counterfeit Marlex Pellets

a. EMAI was a known counterfeiter of plastic products.

27. China has a well-known history of supplying counterfeit plastic raw materials. The medical device maker Bard was forced to recall thousands of its mesh products because it used a counterfeit Marlex.[35] BSC looked at five potential Chinese sellers of Marlex, and ultimately settled on EMAI.[36] EMAI's headquarters sit squarely within the Guandong area of China—an area of rampant counterfeiting with highly publicized busts doing little to slow down the counterfeiting machine it has become.

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[33] *Id.*
[34] Exhibit 9.
[35] Exhibit 15A, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm
[36] Exhibit 16, BSCM138000008924.

28. In July, 2012, BSC's deceptively named "Women's Health Division" (WHD) was notified by the head of another BSC division that EMAI attempted to sell a counterfeit plastic product to another BSC division at about the same time as BSC was buying the EMAI resin.[37] One BSC division rejected counterfeit plastic products from EMAI, its Chinese distributor, yet the WHD of BSC went ahead and purchased EMAI resin to permanently implant in women's bodies—knowing full well its sister division just refused to do business with EMAI.

b. EMAI had no paperwork documenting that the product was authentic Marlex.

29. EMAI claimed its product was Phillips Marlex HGX-030-1 although it lacked the necessary paperwork to prove the authenticity of the resin.[38] The chain of custody of the EMAI resin cannot be documented.[39] EMAI cannot show BSC that Marlex was ever imported into China. EMAI can never show BSC a Certificate of Compliance that, by BSC's own standards, is necessary to accept a product from abroad.

30. If the EMAI resin were authentic and legally imported to China, upon arrival in China, the Marlex would have been tagged by Chinese importers with a "Certificate of Compliance" (C of C) or Certificate of Authority.[40] However, neither a Certificate of Compliance nor a Certificate of Authority were found to authenticate the EMAI resin.[41] BSC executives wildly guessed, without any evidence, that the documents had been lost.[42] That is, BSC executives just made it up.

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[37] Exhibit 17, BSCM11500006904 - BSCM11500006906.
[38] Exhibit 18, BSCM135000000010 – BSCM13500000011.
[39] *Id.*
[40] Exhibit 19, BSCM138000009805.
[41] Exhibit 18, BSCM135000000010 – BSCM13500000011.
[42] Exhibit 20, BSCM12900000074.

31. BSC, acknowledging the importance of product authenticity, emphasized to its purchaser in China that it was imperative to ensure the EMAI resin was in fact Phillps Marlex made in the United States. BSC repeatedly insisted that EMAI procure the C of C so BSC's Chinese purchaser could ensure its accuracy.[43] Ultimately, EMAI, the Chinese distributor was unable to produce the C of C. BSC concluded that the C of C was not "available."

c. Phillips denied that the EMAI product was authentic Marlex.

32. BSC considered obtaining the lot number for the supposed Marlex from EMAI and contacting Phillips to confirm that the EMAI resin was Phillips Marlex. However, BSC noted that Phillips was uninterested in talking to BSC. Remember, "no" meant no—at least it did to Phillips, the manufacturer of the product that didn't want it placed inside the human body. BSC was also concerned that if EMAI learned that BSC intended to use the EMAI resin for medical implantation, then EMAI (like Phillips) might refuse to sell the product.[44]

33. BSC contacted a third party to talk to Phillips on its behalf. On August 31, 2011, the third party reported to BSC that she called her contacts at Phillips and the lot number on the bags being sold by EMAI was not a lot number in Phillips' system.[45] The lot number was fake. BSC's contact could not figure out who the Chinese distributors were, but noted that Phillips would not take responsibility for materials sold in China.[46]

d. Summary of Facts Showing the EMAI Product is counterfeit.

34. At this point in the story, BSC knows that:

[43] Exhibit 21, BSCM13800008925.
[44] Exhibit 22, BSCM13800009802
[45] Exhibit 18, BSCM135000000010 – BSCM13500000011.
[46] *Id.*

- China has a history of selling counterfeit Marlex.
- EMAI had no proof the product was imported into China.
- EMAI had no proof the product was made by Phillips.
- EMAI had no certificate of compliance or authority for its resin.
- EMAI was a known counterfeiter.
- EMAI was a known seller of counterfeit plastic goods.
- EMAI had a history of selling counterfeit plastic goods to BSC.
- Phillips, the alleged manufacturer of the Marlex, confirmed that the lot number shown on the EMAI resin was not a Phillips lot number.

c. In the face of overwhelming evidence that the EMAI resin is counterfeit, BSC relied on the Chinese counterfeiter—second-hand, via email—for assurances that the product was authentic Marlex.

35. BSC, confronted with proof the lot numbers are fake, still needed Marlex. For its transvaginal mesh, it was Marlex or bust. So, BSC chose to rely on EMAI's word that the EMAI resin was, in fact, the Phillips Marlex. Michael Zhao, a BSC Executive, asked the distributor of the resin to let Zhao know if he could find anything related to the lot number. The distributor assured Zhao that the alleged Marlex was all from the same lot. This stunning abdication of BSC's responsibility is explicitly documented in an internal email among high level BSC executives.[47] Rather than rely on the word of the U.S. manufacturer, Phillips, this was fake resin and not its Marlex, BSC chose to rely—second hand through an email from China—that the Chinese resin was authentic Marlex. Now, BSC just needed to get the counterfeit resin out of China.

V. BSC Smuggled the Counterfeit Marlex Out of China

a. Horns of a Dilemma.

[47] Exhibit 23, BSCM129000000085.

36. BSC was on the horns of a dilemma. In the first instance, BSC needed real, authentic Phillips Marlex. Manufacturing its mesh with something other than Marlex HGX-030-01 created the risk, indeed the certainty in the minds of BSC, that its entire mesh line of products, including those sold and implanted into Plaintiff and Class Members, would be disapproved by the FDA. A failure to secure authentic Marlex HGX-030-01 will cost BSC $120,000,000 in sales each year, would wipe out a division of the company, and would cost lots of people their jobs (including those within the mesh division scrambling to find Phillips Marlex).

37. BSC could not find any authentic Marlex HGX-030-01 to purchase. The horns of Boston Scientific's dilemma bore down hard on them. Phillips would not sell its authentic Marlex to BSC; Phillips' customers would not sell it to BSC; and the FDA would not approve an alternate plastic. The last option—the EMAI resin—plainly appeared to be counterfeit. Indeed, EMAI itself had its headquarters in Guandong Province—a known leader in Chinese counterfeiting.

38. BSC decided its best choice, indeed its only choice to keep the doors open, was to try and get the counterfeit EMAI resin out of China and into the U.S. and Belgium for production. To get the counterfeit Marlex out of China, BSC orchestrated a smuggling operation.

b. <u>The Difficulties Created by the Lack of a Certificate of Compliance.</u>

39. The fake Marlex lacked a Certificate of Compliance. The BSC emails repeatedly discussed the need for and the absence of the C of C. The emails disclosed that when a

product like authentic Marlex is imported into China the importer pays an import tax and the importer receives a Certificate of Compliance.[48] The C of C is of paramount importance since it must be shown to Chinese Customs to export the product out of China. To satisfy FDA concerns that authentic Marlex is being used to produce Advantage mesh, BSC would need to show that authentic Marlex was imported from Phillips into China (creating a C of C) and then exported out of China (necessitating a C of C to show Chinese Customs) and then imported into the U.S. or into Belgium.

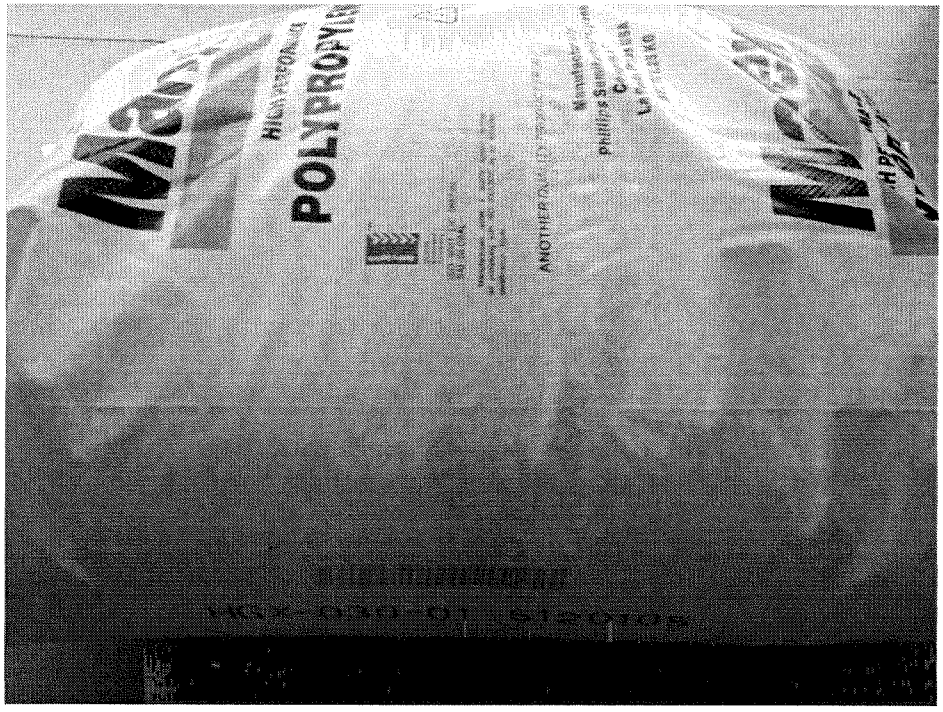
40. Of course, BSC, and EMAI could not ever find the import paperwork because the product was fake, as Phillips told BSC. BSC could be truthful with the Chinese Customs and report that it was exporting from China counterfeit Marlex made in China (thus obviating the need for the C of C), but then BSC would create problems for itself with the FDA. Stated differently, if BSC claimed the EMAI resin is made in China, the product would clear Chinese Customs but BSC would have to notify the FDA of the change. The FDA would likely reject the entire BSC mesh product line, costing BSC $120,000,000 annually. If BSC declared to Chinese Customs the EMAI resin is Phillips Marlex then BSC would avoid the FDA problem, but run the risk the Chinese would discover the deception. Resolving the discrepancy would be time-consuming, costly and might lead the Chinese Customs to confiscate and destroy the EMAI resin.

c. BSC smuggled the counterfeit Marlex out of China by telling the Chinese the product was made in China (obviating the need for the C of C) and then imported the counterfeit Marlex into the U.S. by claiming the product was authentic Marlex (thereby avoiding problems with the FDA).

[48] Exhibit 24, BSCM11500006883

41. BSC purchased 34,000 pounds of fake Marlex from EMAI. 34,000 pounds is about 618 bags that are roughly the size of a fertilizer bag.[49] BSC intended that it would last for 25 years,[50] meaning, absent action from this Court BSC could continue to implant counterfeit Advantage and/or Obtryx (or its other mesh products) into unsuspecting women through the year 2032. The mesh may be implanted into Plaintiff and Class Members (as well as those not even yet born), who will be paying inflated prices for what is, in fact, counterfeit, adulterated mesh worth far less than the authentic material and certainly not what Plaintiff and Class Members paid for when they purchased BSC's product.

42. One EMAI counterfeit Marlex bag looks like this:



[49] The counterfeit Phillips bag lists a net weight of 25 kilograms or approximately 55 pounds.
[50] Exhibit 25, 103_0001.

43. Why the notation that at least one of the bags looked like the photo?[51] When BSC Executive and buyer in China, Michael Zhao, originally contacted EMAI about purchasing Marlex, the EMAI representative reported that he had, it just so happens, sold his last bag. But no problem, he could get more in a week.[52] Then, curiously, the EMAI representative asked for a photograph of a bag of Phillips Marlex. That's curious because the EMAI representative would only need a photo of a bag if he was going to manufacture a counterfeit product (which he had a history of doing, in the Guangdong area where he is) and create a counterfeit Phillips bag to hold the counterfeit Marlex. EMAI would of course have to change the lot number so it was not the same as the photo. Of course, as was ultimately one for at least one bag, Phillips could take the false lot number and confirm the bag and its contents did not come from LaPorte, Texas.[53] But, as it turned out, BSC didn't care.

44. Nonetheless, continuing the facade, in theory, the EMAI distributor had 680 bags of counterfeit Marlex with no proof the bags or contents were legally imported into China and no paperwork to satisfy Chinese Customs when exporting the product to the United States.[54]

45. BSC's original plan called for the counterfeit Marlex to be shipped in five shipments:

- Two bags for testing shipped by air to the U.S.;
- 4,000 pounds or 73 bags shipped by air to the U.S.;
- 10,000 pounds or about 182 bags shipped by ocean transport to Belgium;

[51] Exhibit 18, BSCM13500000010 - BSCM13500000011, August 31, 2011 email notes that the lot number on the bag is not a lot number found in Phillips' system.
[52] Exhibit 26, 106_002 – 106_005.
[53] Exhibit 18, BSCM13500000010 - BSCM13500000011.
[54] Exhibit 27, BSCM13500000971.

- 10,000 pounds or about 182 bags shipped by ocean transport to the U.S.; and
- 10,000 pounds or about 182 bags shipped by ocean transport to the U.S.

46. BCS's plan was to buy two bags of EMAI resin (about 110 pounds), send it by plane to the U.S., and test it to confirm the EMAI resin was authentic Phillips Marlex.[55] Once BSC could confirm that the product was authentic, BSC would ship by air 4,000 pounds of the tested product to relieve the impending shortage.[56] Then, BSC would ship another 30,000 pounds via ocean transport.[57] However, even this plan did not fit BSC's condensed timeline and BSC decided to secure the product immediately, getting all 4,000 pounds to the U.S. as soon as possible. Moreover, crucial BSC documents reveal that BSC's WHD had decided to use the 4,000 pounds regardless of the test results.[58]

d. Smuggling the 4,000 pounds.

47. BSC revised its scheme to immediately smuggle 4,000 pounds out of China even though it was found in a warehouse in Guangdong Province, China (a hub for expert counterfeiters[59]) without import paperwork (C of C). On August 21, 2011, BSC's executive buyer in China of the counterfeit Marlex reported to the Global Supplier for BSC that the 4,000 pounds were shipped by air.[60] In order to avoid a customs inspection, the shipper "over-bagged" the original bag.[61] To over-bag is to put a blank bag over the

[55] Exhibit 28, 75_0001 – 75_0002.
[56] *Id.*
[57] Exhibit 29, 32_0001 – 32_0012.
[58] Exhibit 30, 143_0001; Exhibit 31A
[59] Guangdong Province is a hide-out for counterfeiters. *See*, e.g., Exhibit 30A, article identifying hundreds of counterfeiters caught in 2014. http://www.chinadaily.com.cn/china/2014-07/30/content_18217996.htm. Guangdong is in fact the home of the largest counterfeit goods market in the world. http://appv1.linktv.org/videos/genuine-pride-for-knockoff-goods-in-guangzhou.
[60] Exhibit 31, BSCM12900000086.
[61] Exhibit 20, BSCM12900000074.

original bags. The blank bag contained no markings, indicating the product was made in China.[62] The amount of product was small, the transport was by air, and the EMAI resin in the counterfeit Phillips bag was over-bagged, so the 4,000 pounds were not "inspected."[63] Put simply, BSC—a medical device manufacturer headquartered in the U.S.—smuggled the 4,000 pounds of counterfeit resin out of China.[64]

48. The deception went to high levels within BSC. There is evidence that a BSC executive made separate and contradictory reports about the origin of the resin in order to clear Chinese Customs, and then U.S. Customs.

49. On August 17, 2011, Rob Mullally, Import Export Coordinator asked Charles Smith, Director of Research and Development, about the Chinese product. Smith reported that it was just a bag of Marlex resin as made by Phillips off the shelf, manufactured in Texas.[65] Mullally then confirmed via email that the product was just Marlex being returned to the United States for inter-company use in Marlborough, Massachusetts.[66]

50. This information was used for the shipping instructions for import to the U.S. (to satisfy the FDA). However, Rob Mullally contradicts himself in a later email. When shipping the EMAI resin, Mullally tells the Chinese shipper to report that that the product was made by a Chinese manufacturer to "clear" Chinese customs.[67] The Chinese manufacturer was identified as EMAI from Guangdong Province, China.[68]

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[62] *Id.*
[63] *Id.*
[64] BSC actually received photographs of the forgeries and smuggling operation. On December 1, 2011 BSC executive George Vialle, Director of the Global Supply Chain, circulated photographs for the 4,000 pounds of the resin in the original and over bags. Exhibit 27, BSCM13500000971.
[65] Exhibit 36, BSCM11500005993.
[66] Exhibit 36, BSCM11500005992.
[67] Exhibit 32, BSCM13500000465.
[68] Exhibit 33, BSCM13500000448.

51. After BSC safely smuggled the initial 4,000 pounds of counterfeit Marlex out of China, it set in motion its plans to smuggle the remaining resin out of China to protect its $120,000,000 annual sales and the jobs of those BSC directors and officers directing the smuggling operation. No one mentioned protecting the women the counterfeit resin was soon to infect. BSC leaders were more concerned about the 30,000 pounds of counterfeit resin still stuck in China.

52. This left BSC with the remaining 30,000 pounds to get from China to the United States, or from China to Belgium, where the resin will be turned into filament to make the mesh. To get the 30,000 pounds of EMAI resin out of China without the legal paperwork, BSC would have to "lie" and claim the EMAI resin was made in China.[69] BSC's Chinese purchaser recommended the 30,000 pounds of resin be transferred to different bags with Chinese markings because a large ocean shipment would likely to be inspected by Chinese Customs.[70] If Chinese Customs saw "Phillips" bags, the inspectors would believe the resin was a foreign product which would contradict the paperwork claiming the product was made in China, BSC would be unable to provide paperwork to authenticate the product (C of C), and BSC would "be in trouble."[71] Chinese Customs could very well confiscate the 30,000 pounds of resin without returning them to BSC – costing BSC $120,000,000 per year.

53. We know BSC resolved its problem although the details are a bit murky—as most smuggling operations tend to be. After 19 pages of emails about this problem, George

[69] Exhibit 34, BSCM11500006030.
[70] *Id.*
[71] *Id.*

Vialle suggested the issue be discussed on a conference call.[72] There was no further email discussion that has been produced. The counterfeit Marlex cleared Chinese Customs by claiming to have been made in China.[73] The counterfeit Marlex cleared U.S. Customs by claiming to have been made in the U.S.[74] BSC did not advice the FDA about the lack of authenticity of the resin. Plaintiffs and Class Members wound up with the adulterated, counterfeit, EMAI resin despite paying a premium price for genuine resin.

54. Interestingly, BSC appears to have approached this problem like a drug deal. It divided the 30,000 pounds of resin into three shipments (it had been warned that the bigger the shipment the greater the risk of inspection).[75] It shipped the product on different dates: the Belgium shipment was on May 16, 2012 to Wijnegem; the first ocean shipment to the U.S. was on July 10, 2012 to Gould; and the second ocean shipment to the U.S. was on July 31, 2012 Marlborough or Gould. It shipped the product on separate ships, to different locations.

55. Charles Smith, the executive in charge of this project for BSC, was a fan of using the same over-bagging approach for the 15 tons of material of fake Marlex that it had used to smuggle out the 4,000 pounds via air. BSC completely evaded detection by customs on the first 2 tons air shipped. However, more intricate plans were needed to ship the larger amounts of EMAI resin purchased. Zhao, a BSC executive, discussed with other BSC executives his conversation with the shipper, and the need to conceal the containers from

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[72] Exhibit 35, BSCM11500006807.
[73] Exhibit 32, BSCM13500000465.
[74] Exhibit 36, BSCM11500005992
[75] Exhibit 20, BSCM12900000074. Zhao, the BSC buyer in China, explicitly discussed that the preferred course was to split the ten tons into two containers and have 5 tons in each in case of any accidents. One thing that might have happen was that BSC gets caught and admittedly, BSC would be in trouble. One kind of trouble was that the material would be confiscated, meaning the $120,000,000 would be lost, the division would close and people would lose their jobs.

the inspectors by repacking the full inventory so Chinese customs did not catch them smuggling the alleged Marlex out of China without the proper paperwork.[76] Zhao goes on to talk about what will happen if they are caught by Chinese Customs.[77]

56. BSC executive Charles Smith responded that they could just over bag the products again.[78] At least eight (8) high level BSC executives were included on these emails. No one thought twice about breaking the law. A medical device company's high-level executives and employees were openly discussing smuggling adulterated, counterfeit resin from one of the best counterfeiting provinces in China—Guandong—and not a single employee spoke up to stop it. No one.

57. But BSC employees were speaking up about how to complete the smuggle. BSC discussed bribing Chinese officials to get the counterfeit Marlex out of China. Michael Zhao, BSC Executive and buyer in China, had difficulty finding a distributor in China to provide the exact Marlex that BSC needed, so BSC management encouraged Zhao to bribe the distributors and suppliers for the product and related information. Helge Batz, BSC Director of Materials Management, emailed Zhao and asked whether Zhao offered the distributor money to obtain the information he wanted and told Zhao it was necessary to pull all strings possible.[79]

58. We know BSC lied even to the Chinese about the intended use of the counterfeit Marlex. One can easily imagine that the Chinese counterfeiters would not want attention paid to their fake products which might happen if the fake Marlex was used to make medical devices inserted into the human body in violation of the explicit warnings from Phillips.

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[76] Exhibit 20, BSCM12900000074.
[77] *Id.*
[78] *Id.*
[79] Exhibit 37, 79_0004.

This suspicion did not stop BSC from overtly lying to the distributor about the intended use for the resin.[80] BSC also thought nothing about misleading women about the mesh they were purchasing and implanting in their bodies—mesh marketed as BSC-manufactured and lawful, quality-tested, authentic, and FDA-approved mesh. It wasn't. It was adulterated, counterfeit mesh made from raw materials found in China in the possession of a known counterfeiter of plastics. BSC knew this—Plaintiff and Class Members did not. Plaintiff and Class Members were implanted with this Chinese plastic without knowing any of these facts—facts which should have been disclosed not only to them, but to the proper authorities including the FDA, U.S. Customs, and Chinese Customs. Now, these same women must be informed so they can make a decision, together with their doctors, what to do. Do they risk further complications by further attempts to remove the mesh and its remnants, or do they leave it in despite now knowing it is a counterfeit, Chinese made resin? It is a difficult decision—one that should not be controlled by BSC. If Plaintiff or Class Members consider further mesh "revisions" or surgery (as they are), they must gamble that the next medical device permanently implanted into their bodies is an adulterated, counterfeit device for which they paid far too much money. Just like the Boston Scientific mesh they unfortunately bought.

e. Safety Concerns Based Upon What Can't be Disputed

59. Assume for the moment that BSC is able to conjure paperwork to contradict its own internal emails showing it worked with known counterfeiters from the known counterfeit capitol of the world and a product with a history of being counterfeited. Jump past the lack of documentary proof that the product was imported into China (legally or

[80] Exhibit 22, BSCM13800009802.

otherwise). Jump past Phillips' confirmation that the counterfeit Marlex didn't come from Phillips. Jump past the open discussion about smuggling, over-bagging, bribery, and deceiving the FDA, the injured women, and the doctors and the hospitals. Jump past BSC's declaration that women are its number one priority, that caring is its watchword, a passion for excellence is its guiding beacon.

60. Even jumping past all of those hurdles, as BSC clearly did as it was smuggling counterfeit Marlex out of China, BSC knows that even authentic Marlex is subject to degradation due to exposure to bacteria in the air, to UV rays, sea air, water, salt water, bacteria, heat, cold and to warehouse varmints like insects, rodents, and other unsanitary conditions. Degradation of Marlex causes BSC products to become deformed, rigid, to shrink, to break up into pieces and to cause pain to women and horrible injures to women. Protecting Marlex against exposure to the known elements that cause degradation is crucial. The need to protect Marlex is increased when one factors in the knowledge that degradation and exposure to contaminants is not immediately evident and may not become evident for years. The need to protect the EMAI resin is increased to a fiduciary level with a company like BSC that prides itself on its dedication to women's health.

61. Contrast this need for care with the facts. Assuming that the EMAI resin is truly Phillips Marlex (that was for some reason sitting in a warehouse in an area of China known as a leading counterfeiter), an assumption BSC cannot prove, BSC doesn't know at least the following:

- The date the EMAI resin was manufactured;
- The lot number of the EMAI resin;
- How or when Phillips transported the product to China (or to somewhere else, ending up in China);

- How or when the product was transported in China to the first storage point, the number of times the EMAI resin was moved in China (at least once);
- How or when the product was transported from the last storage point in China to Chinese Customs;
- How or where the EMAI resin was stored (inside, outside, on the floor, in a bag, in the heat, in the cold, in the rain? Bagged? Plastic bags?);
- How the EMAI "Marlex" was handled, exposed, or contaminated during any of its mysterious history or "re-bagging" designed to evade customs officials.

VI. Testing

62. BSC decided to conduct testing to determine whether the counterfeit Marlex was identical to authentic Marlex. To conduct this test, BSC allowed the counterfeiter to select a bag to be tested.[81] BSC then tested a microscopic portion of a single pellet from the bag selected by the counterfeiter. And even though the BSC protocol was specifically designed to ensure the Chinese resin met BSC's arbitrary "equivalency" standards, the test results were awful.

63. First, BSC identified numerous contamination risks associated with shipping the counterfeit Marlex by ocean transport. Given all of the unknowns about the counterfeit Marlex one might imagine a company committed to women's health would take extra steps when evaluating the safety of the counterfeit Marlex. Yet, the testing of the microscopic portion of the single pellet was from the bags shipped by air. The ocean transported bags (30,000 pounds shipped in large containers exposed to the elements) were never tested for biocompatibility.[82]

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[81] Exhibit 38, BSCM11500006926 – BSCM11500006930.

[82] In reality, all of the pellets should have been tested. Saving that, then certainly a representative sample from every bag should have been tested. What halfway prudent buyer lets the seller

64. Luxilon and Proxy did performance tests on the Chinese resin using BSC's arbitrary testing protocol and were aware that the test results showed significant differences in the Chinese material compared to certified Phillips Marlex. Despite this, Luxilon and Proxy knowingly used the substandard, counterfeit Marlex in the manufacturing of the mesh components for BSC.

65. The "testing" of the Chinese polypropylene was substandard and the tests were designed at the outset to ensure the product met "equivalency" standards arbitrarily set by BSC. The single or limited testing that was done used a general plastics testing standard and not the testing standard specific to Marlex. Even still, it showed the use of different catalysts, different molecular strings, different string lengths and a wider variation in the bell curve, indicating a different and/or substandard manufacturing process.[83] The fibers of the resin were weaker. Simply put, the EMAI resin was, in fact, adulterated. The adulterated, counterfeit, Chinese mesh kept failing BSC's tests—so BSC just lowered the standards and waved it on through. No just didn't mean "no" to BSC.

66. Nevertheless, this case is not about the testing. Even if the counterfeit Marlex is identical to authentic Marlex (which BSC's own limited testing confirms the sample is different and not identical) the argument is a red herring. A perfect copy of a $100 bill is still counterfeit. A perfect replica of a Rolex watch is still counterfeit. Advantage mesh made with counterfeit Marlex is still not approved by the FDA and is still counterfeit.

67. Despite Defendants' knowledge that the Chinese material was adulterated and/or counterfeit, BSC, EMAI, Proxy and Luxilon continued with the purchase, distribution,

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choose which microscopic portion of the product to test? Even if BSC manages to invent another test the sample size is woefully, tragically inadequate.

[83] Exhibit 39, Cambridge Polymer Group Testing Data (BSCM07300068256).

manufacturing, advertising, packaging, labeling and selling the counterfeit mesh, along with the counterfeit bagging and/or marking, which resulted. And no one said a thing about it to the FDA or, more important, to the Plaintiff or these Class Members. What had been—all along—a solid "no" about the authenticity of the EMAI resin became a BSC yes. Yes to $120,000,000 in continued annual revenue. Yes to saving the jobs of those at the WHD at BSC. And sadly, yes to implanting Plaintiff and Class Members with counterfeit, adulterated mesh smuggled out of China.

RICO ALLEGATIONS

The Boston Scientific Enterprise

68. BSC is a "person" within the meaning of 18 U.S.C. §1961(3).

69. Based upon Plaintiff's current knowledge, the following persons constitute a group of individuals and entities associated in fact that Plaintiff refers to as the Boston Scientific Enterprise: (1) BSC, (2) EMAI, (3) Proxy, and (4) Luxilon.

70. The Boston Scientific Enterprise is an ongoing organization which engages in, and whose activities affect, interstate commerce. The members of the Boston Scientific Enterprise function as a continuing unit as described below and share the common purpose of smuggling counterfeit Marlex out of China and manufacturing mesh products with the counterfeit Marlex for their individual and collective economic gain.

71. While BSC, EMAI, Proxy and Luxilon participate in and are members of the Boston Scientific Enterprise, they also have an existence separate and distinct from the enterprise. The common goal was to smuggle adulterated and/or counterfeit "Marlex" out of China, circumvent import/export laws of China and the U.S. to "pass" the counterfeit mesh as authentic Marlex, and to avoid the scrutiny of the FDA and

termination of the many mesh sales to Plaintiff, Class Members, and other women throughout the U.S. This generated profits for the enterprise as a whole and for participating individuals.

72. In order to successfully defraud Plaintiff and Class Members in the manner set forth above, BSC, EMAI, Proxy and Luxilon needed a system to obtain and smuggle counterfeit Marlex out of China and manufacture mesh products using the counterfeit Marlex. Additionally, BSC stood to benefit directly from the sales of tens of thousands of mesh products each year made with the counterfeit Marlex. BSC participated in the scheme to avoid a loss of over $120,000,000 per year. EMAI, Proxy and Luxilon also participated in the scheme to avoid the loss of business from BSC.

73. BSC controls and operates the Boston Scientific Enterprise as follows:

(a) By purchasing the counterfeit Marlex from EMAI even after it was confirmed that the lot number on the product did not match a Phillips lot number;

(b) By developing a protocol to test the counterfeit Marlex that ensures that if the Marlex is in fact counterfeit, it will still meet "industry standards;" this included, but is not limited to, reducing standards or protocols to improperly "pass" the Chinese resin as authentic, Marlex mesh or approved product, or directing testing to so find;

(c) By colluding with Proxy and Luxilon to ensure that the counterfeit Marlex "passed" the performance tests pursuant to BSC's protocol; and

(d) By marketing and selling its mesh products which it knows were manufactured using the counterfeit Marlex.

74. As set forth above, the Boston Scientific Enterprise has an ascertainable structure separate and apart from the pattern of racketeering activity in which BSC, EMAI, Proxy and Luxilon engage.

Predicate Acts

75. Section 1961(1) of RICO provides that "racketeering activity" includes any act indictable under 18 U.S.C. §1341 (relating to mail fraud), 18 U.S.C. §1343 (relating to wire fraud), and section 2320 (relating to trafficking in goods or services bearing counterfeit marks). As set forth below, BSC, EMAI, Proxy and Luxilon have and continue to engage in conduct violating each of these laws to effectuate their scheme.

76. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations, or promises, BSC, EMAI, Proxy and Luxilon, in violation of 18 U.S.C. §1341, placed in post offices and/or in authorized repositories matter and things to be sent or delivered by the Postal Service, caused matter and things to be delivered by commercial interstate carrier, and received matter and things from the Postal Service or commercial interstate carriers, including but not limited to counterfeit products, counterfeit bags or marks, invoices, correspondence, payments, lab or test results, samples, and false written materials regarding the mesh product being sold.

77. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations or promises, BSC, EMAI, Proxy and Luxilon also in violation of 18 U.S.C. §1343, transmitted and received by wire matter and things which include but are not limited to counterfeit product, invoices, correspondence, payments, lab or test results, samples, photographs or descriptions of counterfeit bags or marks, and false written materials regarding the mesh product being sold.

78. The matter and things sent by BSC, EMAI, Proxy and Luxilon via the Postal Service, commercial carrier, wire or other interstate electronic media include, *inter alia,*

counterfeit Marlex which was smuggled out of China and into the United States, and false information regarding the mesh products implanted into Plaintiff and Class Members.

79. Other communications sent through or received from the Postal Service, commercial carrier, or interstate wire transmission by BSC, EMAI, Proxy and Luxilon included information or communications in furtherance of or necessary to effectuate the scheme.

80. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations, or promises for financial gain, BSC, EMAI, Proxy and Luxilon are in violation of 18 U.S.C. § 2320 by intentionally trafficking in goods and knowingly using a counterfeit mark on or in connection with the goods.

81. EMAI intentionally sold BSC 34,000 pounds of counterfeit Marlex for financial gain. The counterfeit markings on the bags intentionally sold to BSC were identical to, or substantially indistinguishable from, Phillips' mark, which is registered in the United States Patent and Trademark Office (USPTO), and in use. The counterfeit marks were applied and used in connection with the goods for which the mark is registered in the USPTO. Additionally, BSC's and EMAI's use of the counterfeit marking on the bag is likely to cause confusion, mistake, or to deceive. Defendant BSC's and EMAI's creation and duplication of Phillips' bags and Proxy and Luxilon's willful blindness to these unlawful acts constitutes counterfeiting.

82. BSC intentionally purchased at least 30,000 pounds of the counterfeit Marlex, despite having knowledge that the lot number on the counterfeit label was not a lot number recognized by Phillips.

83. After purchase of the counterfeit Marlex, BSC contracted with Proxy and Luxilon to test the product knowingly obtained from China. The test results from both Proxy and Luxilon showed that the Chinese Marlex was not in fact Phillips Marlex and the material did not perform the same. Despite having knowledge that the resin product from China was counterfeit Marlex, Luxilon intentionally manufactured mesh fibers using the counterfeit Marlex. Despite having knowledge that the resin product from China was counterfeit Marlex, Proxy intentionally wove mesh sheets using the filament that was manufactured with the counterfeit Marlex.

84. Despite having knowledge that the resin product from China was counterfeit Marlex, BSC, EMAI, Proxy, and Luxilon fraudulently imported, exported, and manufactured, marketed and sold mesh products which were manufactured with the counterfeit Marlex, but represented to Plaintiff, Class Members and the FDA that authentic Phillips Marlex was used to manufacture the mesh products.

85. BSC's, EMAI's, Proxy's and Luxilon's overt acts of fraud, misrepresentations, acts of concealment, and failures to disclose were knowing and intentional, and made for the purpose of deceiving Plaintiff and Class Members and for the purpose of financial gain from products made with the counterfeit Marlex which were sold to and implanted in Plaintiff and Class Members.

86. BSC, EMAI, Proxy and Luxilon either knew, recklessly disregarded, or were willfully blind to the fact that the misrepresentations and omissions regarding the authenticity of the Marlex described above were material and would be relied upon by Plaintiff and Class Members. Plaintiff and Class Members were defrauded as a result of the misrepresentations and omissions as set forth above.

87. As a result, BSC, EMAI, Proxy and Luxilon have fraudulently imported, exported, and manufactured, marketed and distributed the counterfeit mesh products sold and implanted to Plaintiff and Class Members. These Defendants were able to charge for services based upon their participation in fraudulently importing, exporting, manufacturing, marketing, and selling mesh products made with the counterfeit Marlex.

88. Defendants' introduction into interstate commerce medical devices, specifically counterfeit transvaginal mesh, which were misbranded in that the product labeling contained false and misleading information identifying the devices as authentic transvaginal mesh manufactured with Marlex, when in reality the mesh was not made with Marlex is criminal conduct pursuant to §§ 21 U.S.C. 331(a), 331(a)(1), and 352(a).

89. Plaintiff and Class Members have been injured in their business or property by Defendants' overt acts of mail fraud, wire fraud, and intentionally trafficking goods bearing counterfeit marks.

Pattern of Racketeering Activity

90. BSC, EMAI, Proxy and Luxilon have engaged in a "pattern of racketeering activity," as defined by 18 U.S.C. § 1961(5), by committing or aiding and abetting in the commission of at least two acts of racketeering activity, *i.e.*, indictable violations of 18 U.S.C. §§1341, 1343, and 2320, as described above, within the past ten years.

91. BSC, EMAI, Proxy and Luxilon have committed multiple acts of racketeering activity. BSC's purchase of the counterfeit Marlex and wire payment for the product occurred on two separate dates, the illegal export of the polypropylene from China bearing counterfeit markings occurred on at least four different dates, the illegal import of the counterfeit Marlex bearing counterfeit markings occurred on at least four separate dates, all proving

separate and definable predicate acts of racketeering activity. Additionally, Plaintiff's and Class Members' mesh implants manufactured from counterfeit Marlex were manufactured, sold, and transported interstate on different dates, proving separate and definable predicate acts of racketeering activity. The Boston Scientific Enterprise provided false information regarding the mesh products implanted into Plaintiff and Class Members through mail or interstate wire transfer on many different dates, proving separate and definable predicate acts of racketeering activity. Each act of racketeering activity was related, had a similar purpose, involved the same or similar participants and method of commission, had similar results, and impacted similar victims, including Plaintiff and Class Members.

92. The multiple acts of racketeering activity which Defendants committed and/or conspired to commit, or aided and abetted acts, were related to each other and amount to and pose a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity" as defined in 18 U.S.C. § 1961(5).

CLASS ACTION ALLEGATIONS

93. Plaintiff brings this action against Defendants on her own behalf and, pursuant to Rules 23(a) and (b) of the Federal Rules of Civil Procedure, as a class action on behalf of a class of persons similarly situated which include the following:

> **All persons who were implanted with a Boston Scientific Corporation transvaginal mesh product after September, 2012.**

94. Excluded from the Class are Defendants, any entity in which one or more of the Defendants has a controlling interest or is a parent or subsidiary of said Defendants, any individual or entity already represented by counsel for these offenses, any entity that is controlled by one of more of the Defendants and any of their officers, directors,

employees, affiliates, legal representatives, heirs, predecessors, successors and assigns, this Court and any of its immediate staff.

95. Upon information and belief, there are thousands of members of the Class. Accordingly, the Class is so numerous that joinder of all members is impracticable. The Class is ascertainable, as the names and addresses of all Class Members can be identified in business records maintained by doctors to whom BSC's transvaginal was sold, as well as Defendants' sales and other records.

96. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual Class Members. Such common questions include, *inter alia*:

a. Whether BSC, EMAI, Proxy, and/or Luxilon have engaged in a scheme to smuggle counterfeit Marlex out of China and into the United States and/or Belgium;

b. Whether BSC, EMAI, Proxy, and/or Luxilon have engaged in a scheme to manufacture mesh products made from counterfeit Marlex;

c. Whether BSC, EMAI, Proxy, and/or Luxilon have engaged in mail and wire fraud;

d. Whether BSC, EMAI, Proxy, and/or Luxilon have engaged in trafficking of goods bearing counterfeit marks;

e. Whether BSC, EMAI, Proxy, and/or Luxilon have engaged in a pattern of racketeering activity;

f. Whether BSC, EMAI, Proxy, and/or Luxilon's overt and predicate act in violation of 18 U.S.C. § 1962(c) proximately caused injury to Plaintiff and Class Members' business or property;

g. Whether BSC, EMAI, Proxy, and/or Luxilon constitute an enterprise within the meaning of 18 U.S. C. § 1961(4);

h. Whether BSC made intentionally or negligent misrepresentations in connection with the manufacturing, production, marketing, advertising,

packaging, labeling, distribution, and/or sale of BSC mesh products containing the counterfeit Marlex.

i. Whether BSC violated W. Va. Code §41A-6-104 relating to unlawful deceptive trade practices, or violated other deceptive act laws;

j. Whether BSC's practices in connection with the manufacturing, production, marketing, advertising, packaging, labeling, distribution, and/or sale of BSC mesh products containing the counterfeit Marlex unjustly enriched Defendants at the expense of, and to the detriment of, Plaintiff and Class Members.

k. Whether Defendants' conduct as set forth above injured consumers and if so, the extent of the injury.

97. Plaintiff's claims are typical of the claims of the Class Members because they originate from the same illegal, fraudulent, and confiscatory practices of Defendants. Defendants acted in the same way toward Plaintiff and Class Members.

98. Plaintiff will fairly and adequately protect the interests of the Class Members, is committed to the vigorous prosecution of this action, has retained counsel competent and experienced in class litigation and has no interests antagonistic to or in conflict with those of the Class. As such, Plaintiff is an adequate Class representative.

99. The prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for the party opposing the Class.

100. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Further, the expense and burden of individual litigation make it impossible for all the Class Members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

AND AS FOR THE FIRST CAUSE OF ACTION

VIOLATION OF 18 U.S.C. § 1962(c)

101. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

102. This claim for relief arises under 18 U.S.C. §1962(c). As set forth above, BSC, EMAI, Proxy, and Luxilon have violated 18 U.S.C. §1962(c) by conducting or participating, directly or indirectly, in the conduct of the affairs of the Boston Scientific Enterprise through a pattern of racketeering.

103. As a direct and proximate result, Plaintiff and Class Members have been injured in their business or property by the predicate acts which make up Defendants' patterns of racketeering activity through the Boston Scientific Enterprise.

104. Specifically, Plaintiff and Class Members have been economically injured in their business or property by purchasing counterfeit products which were medically implanted in their bodies as a result of the scheme.

AND AS FOR THE SECOND CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION

105. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

106. Defendant BSC has represented to the public, including Plaintiff and Class Members, as well as the FDA, through promotion, marketing, informational materials, application for approval, packaging, labeling, and other means that its mesh products had characteristics and qualities, that they did not have, specifically, that the products were manufactured using authentic, certified Marlex and that they were safe to use in permanently implantable devices.

107. Defendant BSC's representations were false in that the mesh products manufactured with counterfeit Marlex, not made with certified Phillips Marlex as represented and approved by the FDA and were not safe for use in the human body.

108. Defendant BSC made the misrepresentations alleged herein intentionally to deprive Plaintiff and Class Members of property or otherwise causing damage.

109. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its Advantage transvaginal mesh products, and in justifiable reliance thereon, purchased the BSC product.

110. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on counterfeit products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendants, and thereby lost money by purchasing a product that was not what it was represented to be, which was worth less that they paid for, and which they would not have purchased but for the misrepresentations.

111. Plaintiff and Class Members, in purchasing and being implanted with BSC's mesh products as alleged herein, did rely on Defendant BSC's misrepresentations, all to their detriment.

AND AS FOR THE THIRD CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

112. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

113. Defendant BSC has represented to the public, including Plaintiff and Class Members, as well as the FDA, through promotion, marketing, informational materials, application for

approval, packaging, labeling, and other means that its mesh products had characteristics and qualities, that they did not have, specifically, that the products were manufactured using Marlex and that they were safe to use in permanently implantable devices.

114. Defendant BSC's representations were false in that the mesh products manufactured with counterfeit Marlex, not made with certified Phillips Marlex as represented and approved by the FDA and were not safe for use in the human body.

115. Defendant BSC made the false representations alleged herein with the intention of inducing Plaintiff and Class Members to purchase and/or use BSC mesh products.

116. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its Advantage transvaginal mesh product, and in justifiable reliance thereon, purchased the BSC product.

117. At the time Defendant BSC made the misrepresentations alleged herein, Defendant BSC has no reasonable grounds for believing the representations to be true.

118. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on counterfeit products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendant BSC, and thereby lost money by purchasing a product that was not what it was represented to be, which was worth less that they paid for, and which they would not have purchased but for the misrepresentations.

119. Plaintiff and Class Members, in purchasing and being implanted with BSC's mesh products as alleged herein, did rely on Defendant BSC's representations, all to their detriment, including economic damage.

AND AS FOR THE FOURTH CAUSE OF ACTION
UNFAIR AND DECEPTIVE ACTS AND PRACTICES
IN VIOLATION OF W. VA. CODE §41A-6-103

120. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

121. Defendant BSC's sale of mesh products manufactured using counterfeit and likely contaminated Marlex caused the likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services. Because the mesh products sold to Plaintiff and Class Members were not made from authentic Marlex polypropylene, the products were not approved by the FDA, as BSC represented to Plaintiff and Class Members. This conduct is unlawful pursuant to W. Va. Code §41A-6-104 as this practice is defined as an unfair or deceptive act or practice by W. Va. Code §41A-6-102(7)(B) and §41A-6-102(7)(E).

122. Defendant BSC used deceptive representations of designations of geographic origin in connection with the mesh products sold to Plaintiff and Class Members which is unlawful pursuant to W. Va. Code §41A-6-104 as this practice is defined as an unfair or deceptive act or practice by W. Va. Code §41A-6-102(7)(D). Specifically, BSC represented that the resin used to manufacture the mesh was authentic Marlex made in the U.S.A., but in fact, the Marlex was counterfeit and manufactured in China.

123. Defendant BSC represented to Plaintiff and Class Members that its mesh products were a particular standard and quality, specifically, manufactured with authentic Marlex. However, the mesh products sold to Plaintiff and Class Members did not meet the

represented standard because the mesh products were manufactured using counterfeit and likely contaminated Marlex. This conduct is unlawful pursuant to W. Va. Code §41A-6-104 as this practice is defined as an unfair or deceptive act or practice by W. Va. Code §41A-6-102(7)(G), and violates other deceptive practices acts.

124. BSC advertised that its mesh products were manufactured using authentic Marlex with the intent not to sell Plaintiff and Class Members mesh products manufactured using authentic Marlex and intended this result. Instead, BSC knew Plaintiff and Class Members would be sold mesh products manufactured with counterfeit and likely contaminated Marlex. This conduct is unlawful pursuant to W. Va. Code §41A-6-104 as this practice is defined as an unfair or deceptive act or practice by W. Va. Code §41A-6-102(7)(I).

125. BSC advertised, printing, and publishing false statements with regard to the sale of its mesh products to Plaintiff and Class Members, specifically that the mesh products it sold Plaintiff and Class Members were manufactured using authentic Marlex, when in fact, the mesh products it sold Plaintiff and Class Members were manufactured using counterfeit and likely contaminated Marlex. This conduct is unlawful pursuant to W. Va. Code §41A-6-104 as this practice is defined as an unfair or deceptive act or practice by W. Va. Code §41A-6-102(7)(N).

126. Plaintiff and Class Members have suffered actual, out-of-pocket costs proximately caused by Defendants BSC's violations of W. Va. Code §41A-6-104. The misrepresentations, omissions and deceptive acts by Defendant BSC caused Plaintiff and Class Members to enter into the transactions which result in their damages.

AND AS FOR THE FIFTH CAUSE OF ACTION
FRAUD

127. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

128. BSC is liable to Plaintiff and Class Members for fraud. Under West Virginia law a Defendant is liable for fraud if: (1) the defendant committed an act claimed to be fraudulent or induced a fraudulent act; (2) the act was material, false, and plaintiff's reliance on the act was justifiable; and (3) plaintiff was damaged as a result of her reliance on defendant's act. *Horton v. Tyree*, 104 W.Va. 238, 242, 139 S.E. 737 (1927); Syl. Pt. 5, *Kidd v. Mull*, 215 W.Va. 151, 595 S.E.2d 308 (2004); *Sneberger v. Morrison*, 776 S.E.2d 156, 2015 W. Va. LEXIS 732 (W. Va. 2015).

129. Boston Scientific smuggled counterfeit Marlex HGX-030-1 resin pellets into to the United States and Belgium.[84] Zhao, a BSC executive, discussed with other BSC executives his conversation with the shipper, and the need to conceal the containers from the inspectors by repacking the full inventory so Chinese customs did not catch them smuggling the alleged Marlex out of China without the proper paperwork, and discussed what would happen if they are caught by Chinese Customs.[85]

130. BSC used this counterfeit product as the base material shipped to Proxy and Luxilon, to be manufactured into all mesh products relevant herein. The FDA requires device manufacturers to submit a new application for clearance if the manufacturer changes any material within a permanent implant device. BSC failed to submit a request for clearance of the counterfeit material in its mesh products. Rather, BSC deceptively promoted,

[84] Exhibit 20, BSCM12900000074.
[85] Exhibit 20, BSCM12900000074.

marketed, packaged, labeled, sold and distributed this mesh as being manufactured with authentic Marlex and approved by the FDA.

131. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its transvaginal mesh products to their detriment, and in justifiable reliance thereon, purchased the BSC product.

132. BSC sold mesh manufactured with counterfeit Marlex to Plaintiffs and Class Members under the false premise that the product(s) were cleared by the FDA. BSC's goal was to maintain its $120,000,000 revenue per year.[86]

133. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on BSC products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendant BSC, and thereby lost money by purchasing a product that was not what it was represented to be, which was worth less that they paid for the, and which they would not have purchased but for the fraud.

AND AS FOR THE SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT

134. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

135. Defendant BSC has benefited from its unlawful acts by receiving excessive revenue derived from the sales of mesh products represented as being manufactured with Marlex. Defendant BSC appreciated and/or knew the benefit of the receipt of such excessive revenue. This excessive revenue has been received by Defendant BSC at the expense of

[86] Exhibit 6.

Plaintiff and Class Members, under circumstances in which it would be inequitable for Defendant BSC to be permitted to retain the benefit.

136. Plaintiff and Class Members are entitled to the establishment of a constructive trust consisting of the benefit conferred upon Defendant BSC in the form of its excessive revenue derived from the sale of mesh products manufactured with counterfeit Marlex from which Plaintiff and Class Members may make claims on a pro rata basis for restitution.

AND AS FOR THE SEVENTH CAUSE OF ACTION
INJUNCTIVE AND DECLARATORY RELIEF

137. Plaintiff hereby incorporates by reference as if fully set forth herein all of the preceding paragraphs.

138. BSC has misrepresented to Plaintiff and Class Members that their mesh products contained Phillips Marlex and were safe for use even though the mesh was manufactured using counterfeit and likely contaminated Marlex illegally exported and imported from China and the use of the product has resulted in economic damage to Plaintiff and Class Members. Plaintiff and Class Members paid for a genuine, tested, and lawful product, but instead got an adulterated and/or contaminated one worth far less than paid.

139. Plaintiff and Class Members ask the Court to enjoin BSC from selling all counterfeit mesh production manufactured with counterfeit Marlex and from continuing to use the counterfeit Marlex pellets in all of its chemical forms. Plaintiff and Class Members, many who already underwent or possibly will further undergo mesh surgery, also request the Court order BSC to warn the public about the counterfeit Advantage mesh by issuing the following warning:

WARNING: Boston Scientific Corporation Advantage mesh,

which makes up all its transvaginal mesh, is counterfeit and is made from counterfeit Marlex resin. It may also be an adulterated medical device. You should fully explore all treatment options with your caregiver before using any BSC transvaginal mesh products. If you already have been implanted with BSC transvaginal mesh, you should consult your doctor about your options.

140. Plaintiffs and Class Members further request that the warning be posted on the opening page of the BSC website; placed on the most prominent ad page of the Sunday paper of the top 100 newspapers in the United States as measured by Sunday circulation; by providing to the FDA and all known purchasers of BSC mesh products a copy of this motion including unredacted copies of the supporting documents and the Court's own finding and conclusions.

141. Defendant BSC should be enjoined from currently selling mesh was manufactured using counterfeit Marlex and enjoined from engaging in these practices in the future. Without such relief immediate and irreparable injury, loss, and damage will result.

JURY DEMAND

142. Plaintiff requests a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in her favor and in favor of the Class Members against Defendants as follows:

A. Determining that this action may be maintained as a class action under FED. R. CIV. P. 23(a) and (b);

B. Declaring that Defendants have committed the violations alleged herein;

C. Ordering Defendants to pay treble the amount of damages suffered by Plaintiff and the Class as a result of Defendants' violations of Section 1962(c) of RICO;

D. Awarding Plaintiff and Class Members a temporary restraining order, a temporary injunction, and a permanent injunction relief by prohibiting, restraining and enjoining Defendants from engaging in the conduct complained of herein, including, inter alia, manufacturing, production, marketing, advertising, packaging, labeling, distribution, and/or sale of BSC mesh products containing the counterfeit Marlex polypropylene.

E. Awarding Plaintiff and Class Members refunds, damages, general damages, punitive damages, consequential damages, other special damages, attorneys' fees and other reasonable costs;

F. Awarding Plaintiff and Class Members all statutory damages available under the claims asserted;

G. For payment of costs of suit incurred;

H. Pre- and post-judgment interest at the maximum rate allowable by law on any amounts awarded; and

I. Granting such other relief as this Court deems to be just and proper.

DATED: January 12, 2016

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